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PATENT

Attorney Docket No. UM-04491

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## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: James R. Baker, Jr. *et al.*

Serial No.: 09/751,059

Group No.:

Filed: 12/29/00

Examiner:

Entitled: Antimicrobial Compositions And Methods Of Use

INFORMATION DISCLOSURE  
STATEMENT TRANSMITTALAssistant Commissioner for Patents  
Washington, D.C. 20231

## CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8(a)(1)(i)(A)

I hereby certify that this correspondence (along with any referred to as being attached or enclosed) is, on the date shown below, being deposited with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.


Dated: June 19, 2002By: 

Mary Ellen Waite

Sir or Madam:

Enclosed please find an Information Disclosure Statement and Form PTO-1449, including copies of the references contained thereon, for filing in the U.S. Patent and Trademark Office.

This Information Disclosure Statement is being filed before the issuance of a first Office Action and therefore, Applicants believe no fee is required but if the Commissioner deems otherwise, the Commissioner is hereby authorized to charge any additional fee or credit overpayment to our Deposit Account No. 08-1290. An originally executed duplicate of this transmittal is enclosed for this purpose.

Dated: June 19, 2002  
David A. Casimir  
Registration No. 42,395MEDLEN & CARROLL, LLP  
101 Howard Street, Suite 350  
San Francisco, California 94105  
608/218-6900

FORM PTO-1449 (Modified)		U.S. Department of Commerce Patent and Trademark Office		Attorney Docket No.: UM-04491	Serial No.: 09/751,059
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (Use Several Sheets If Necessary)				Applicant: James R. Baker, Jr. <i>et al.</i>	
(37 CFR § 1.98(b))				Filing Date: 12/29/00	Group Art Unit:

U.S. PATENT DOCUMENTS							
Examiner Initials	Cite No.	Serial / Patent Number	Issue Date	Applicant / Patentee	Class	Subclass	Filing Date
	1	5,618,840	04/08/95	Wright	514	549	05/18/95
	2	5,547,677	08/20/96	Wright	424	401	05/20/94
	3	5,549,901	08/27/96	Wright	424	401	10/13/94
	4	5,700,679	12/23/97	Wright	435	238	06/07/96
	5	5,662,957	09/02/97	Wright	426	605	05/03/96
	6	5,510,104	04/23/96	Allen	424	94.4	06/02/95
	7	5,103,497	04/07/92	Hicks	385	117	01/03/91
	8	4,895,452	01/23/90	Yiournas <i>et al.</i>	366	173	03/03/88
	9	6,015,832	01/18/00	Baker, Jr., <i>et al.</i>	514	546	12/31/97
	10	5,108,660	04/28/92	Michael	252	545	12/21/90
	11	6,361,787	3/26/02	Shaheen <i>et al.</i>	424	406	5/27/98
	12	6,348,187	2/19/02	Pan <i>et al.</i>	424	53	8/3/98

FOREIGN PATENTS OR PUBLISHED FOREIGN PATENT APPLICATIONS								
		Document Number	Publication Date	Country / Patent Office	Class	Subclass	Translation	
							Yes	No

OTHER DOCUMENTS (Including Author, Title, Date, Relevant Pages, Place of Publication)		
13	Alasri <i>et al.</i> , "Sporicidal properties of peracetic acid and hydrogen peroxide, alone and in combination, in comparison with chlorine and formaldehyde for ultrafiltration membrane disinfection." <i>Can. J. Microbiol.</i> 1993; 39: 52-60.	
14	Barrett and Inglis "Growth purification and titration of influenza viruses." In: Mahy WJ. ed. <i>Virology. a Practical approach.</i> IRL. Press, 1985; 119-151. This reference is a book and is not being submitted at this time but if the Examiner requests the referenc it will be submitted.	
15	Baragi <i>et al.</i> , "Transplantation of transduced Chondrocytes protects articular cartilage from intedeukin 1 -induced extracellular matrix degradation." <i>J Clin Invest</i> 1995; 96: 2454-2460	
16	Beauchamp <i>et al.</i> , "A critical review of the toxicology of glutaraldehyde." <i>Crit. Rev. Toxicol.</i> 1992; 22:143-174.	
17	Berkelman <i>et al.</i> , "Emerging infectious diseases in the United States, 1993." <i>J Infect Dis.</i> 1994 Aug; 170(2):272-7	
18	Burdon <i>et al.</i> , "Experimental infection of mice with <i>Bacillus cereus</i> : studies of pathogenesis and pathologic changes." <i>J. Infect. Dis.</i> 1967; 117: 307-316	
19	Burdon and Wende. "On the differentiation of anthrax bacilli from <i>Bacillus cereus</i> ." <i>J. Infect. Dis.</i> 1960; 107: 224-234.	
20	Chatlyne <i>et al.</i> , "A lipid emulsion with effective virucidal activity against H IV-1 and other common viruses." <i>Foundation for Retrovirology and Human Health</i> , 3rd Conference on Retroviruses and Opportunistic Infections, Washington D.C., U.S.A., 1996; Abstract #351. This reference is a book and is not being submitted at this time but if the Examiner requests the referenc it will be submitted.	
21	Dragon and Rennie "The ecology of anthrax spores: Tough but not invincible." <i>Can. Vet. J.</i> 1995; 36: 295-301	
22	Drobniowski " <i>Bacillus cereus</i> and related species." <i>Clin. Microbiol. Rev.</i> 1993; 6: 324-338	

Examiner:	Date Considered:
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<b>EXAMINER:</b>	Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
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OTHER DOCUMENTS (Including Author, Title, Date, Relevant Pages, Place of Publication)					
	23	Fritz <i>et al.</i> , "Virus validation of plasma-derived products produced by Pharmacia, with particular reference to immuno Globulins." <i>Blood Coagulation and Fibrinolysis</i> 1994; 5 (Suppl. 3): S37-S44. This reference is a book and is not being submitted at this time but if the Examiner requests the reference it will be submitted.			
	24	Florence "Non-ionic surfactant vesicles: preparation and characterization." In: Gregoriadis G. ed. <i>Liposome Technology. Liposome Preparations and Related Techniques</i> . 2nd ed. Vol. 1. CRC Press, 1993. This reference is a book and is not being submitted at this time but if the Examiner requests the reference it will be submitted.			
	25	Foster and Johnstone "Pulling the trigger: the mechanism of bacterial spore germination." <i>Molecular Microbiology</i> 1990;4:137-141.			
	26	Franz <i>et al.</i> , "Clinical recognition and management of patients exposed to biological warfare agents." <i>JAMA</i> 1997; 278: 399-411			
	27	Fritz <i>et al.</i> , "Pathology of experimental anthrax in the rhesus monkey." <i>Lab. Invest.</i> 1995; 73: 691-702			
	28	Goodman & Gilman's "The Pharmacological Basis of Therapeutics" Eds. Hardman <i>et al.</i> , 9th Edition, Pubi. McGraw Hill, 1996; chapters 43 through 50. This reference is a book and is not being submitted at this time but if the Examiner requests the reference it will be submitted.			
	29	Graham <i>et al.</i> , "Characteristics of a human cell line transformed by DNA from human adenovirus type 5." <i>J Gen Virol</i> 1977; 36: 59-74			
	30	Halvorson and Church, <i>Bacteriol Rev</i> 1957, 21:112			
	31	Hamouda <i>et al.</i> , "Microbiocidal effects of liposome-like microemulsions on pathogenic Gram negative bacteria." In: American Society for <i>Microbiology</i> , 98th General Meeting, Atlanta, Georgia, U.S.A., 1998; Abstract A-52.			
	32	Hamouda <i>et al.</i> , "A novel surfactant nanoemulsion with broad-spectrum sporicidal activity against <i>Bacillus</i> species". <i>Journal Infectious Disease</i> 1999. 180:1939-1949			
	33	Hayden <i>et al.</i> , "Plaque inhibition assay for drug susceptibility testing of influenza viruses." <i>Antimicrob Agents Chemother.</i> 1980 17: 865-870			
	34	Herlocher <i>et al.</i> , "Sequence comparison of AIAA/6/60 influenza viruses: mutations, which may contribute to attenuation." <i>Virus Res.</i> 1996; 42:11-25			
	35	Hermonat <i>et al.</i> , "The spermicide nonoxonyl-9 does not inactivate papillomavirus." <i>Sexually Trans Dis</i> 1992; 19: 203-205.			
	36	Hess <i>et al.</i> , "Epidermal toxicity of disinfectants." <i>Amer. J. Dent.</i> 1991; 4: 51-56.			
	37	Hills, <i>J Gen Microbiol</i> 4:38,1950			
	38	Horowitz <i>et al.</i> , "Solvent/detergent-treated plasma: a virus-inactivated substitute for fresh frozen plasma." <i>Blood</i> 1992; 79: 826-831			
	39	Huang <i>et al.</i> , "Antiviral activity of some natural and synthetic sugar analogues." <i>FEBS Letters.</i> 1991; 291: 199-202			
	40	Ivins <i>et al.</i> , "Experimental anthrax vaccines: efficacy of adjuvants combined with protective antigen against an aerosol <i>Bacillus anthracis</i> spore challenge in guinea pigs." <i>Vaccine</i> 1995; 13: 1779-1784			
	41	Jackson <i>et al.</i> , "PCR analysis of tissue samples from the 1979 Sverdlovsk anthrax victims: The presence of multiple <i>Bacillus anthracis</i> strains in 10 different victims." <i>PNAS</i> 1998; 95:1224-1229			
	42	Karalvanova and Spiro RG. "Sulphation of N-linked oligosaccharides of vesicular stomatitis and influenza virus envelope glycoproteins: host cell specificity, subcellular localization and identification of substituted saccharides." <i>Bioch J</i> 1998; 329: 511-518			
	43	Lamanna and Jones "Lethality for mice of vegetative and spore forms of <i>Bacillus cereus</i> and <i>Bacillus cereus</i> -like insect pathogens injected intraperitoneally and subcutaneously." <i>J. Bact.</i> 1963; 85: 532-535			
	44	Lamb and Krug "Orthomyxoviridae: The viruses and their replication." In: Fields BN. Knipe DM. Howley PM. eds. <i>Fields Virology</i> , 3rd ed., Philadelphia Pennsylvania, U.S.A., Lippincott-Raven Publishers, 1996; 1353-1395.			
	45	Lee "Review: in vitro spermicidal tests." <i>Contraception</i> 1996; 54: 131-147			
	46	Lim and Chae "A simple assay for DNA transfection by incubation of the cells in culture dishes with substrates for beta-galactosidase." <i>Biotechniques</i> 1989; 7: 576-579.			
	47	Lineaweaver <i>et al.</i> , "Topical antimicrobial toxicity." <i>Arch. Surg.</i> 1985; 120: 267-270.			
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	48	Maha and Igasani "The effect of nonionic detergent on dengue and Japanese encephalitis virus antigens in antigen detection ELISA and <del>ELISA</del> ELISA." <i>Southeast Asian J Trop Med Pub Health</i> 1997; 28: 718-722. This reference is a book and is not being submitted at this time but if the Examiner requests the referenc it will be submitted.			
	49	Mammen <i>et al.</i> , "Effective inhibitors of hemagglutination by influenza virus synthesized from polymers having active ester groups. Insight into mechanism of inhibition." <i>J Med Chem</i> 1995; 38: 4179-4190.			
	50	Mendel <i>et al.</i> , "Oral administration of a prodrug of the influenza virus neuraminidase inhibitor GS 4071 protects mice and ferrets against influenza infection." <i>Antimicrob Agents Chemother</i> 1998; 42: 640-646.			
	51	Meselson <i>et al.</i> , "The Sverdlovsk anthrax outbreak of 1979." <i>Science</i> 1994; 266:1202-1208.			
	52	Mobley "Biological warfare in the twentieth century: lessons from the past, challenges for the future." <i>Military Med.</i> 1995; 160: 547-553			
	53	Morgan "A brief review of formaldehyde carcinogenesis in relation to rat nasal pathology and human health risk assessment." <i>Toxicol Pathol</i> 1997; 25: 291-307			
	54	Mosmann J. <i>Immun. Methods</i> 1983, 65, 55-63 Mulder and Hers "Influenza." Wolter-Noordhoff Publishing, 1972.			
	55	O'Hagan "Recent advances in vaccine adjuvants for systemic and mucosal administration." <i>J Pharmacy Pharmacol</i> 1998; 50: 1 -10			
	56	Pile <i>et al.</i> , "Anthrax as a potential biological weapon." <i>Arch. Intern. Med.</i> 1998; 158: 429-434			
	57	Portocala <i>et al.</i> , "Immunoelectrophoretic characterization of Sendai virus antigens." <i>Virologie</i> 1976; 27: 261-264			
	58	Russell "Bacterial spores and chemical sporicidal agents." <i>Clin. Micro</i> 1990; 3: 99-119			
	59	Schulze "Effects of glycolysation on the properties and functions of influenza virus hemagglutinin." <i>J Infect Dis</i> 1997; 176 (Suppl. 1): S24-28.			
	60	Shibata "Germination of inactivated spores of <i>Bacillus cereus</i> T. Effect of preincubation with L-alanine or inosine on the subsequent germination." <i>Japan. J. Microbiol.</i> 1976; 20: 529-535			
	61	Smith <i>et al.</i> , "Dihydropyrancarboxamides related to Zanamivir: a new series of inhibitors of influenza virus sialidases. 1. Discovery, synthesis biological activity, and structure-activity relationships of 4-guanidino and 4-amino-4H-pyran-6-carboxamides." <i>J Med Chem</i> 1998; 41: 787-797			
	62	Titball and Manchee "Factors affecting the germination of spores of <i>Bacillus anthracis</i> ." <i>J. Appl. Bact.</i> 1987; 62: 269-273.			
	63	Waghorn and Goa, "Zanamivir." <i>Drugs</i> 1998; 55: 721-725.			
	64	Welkos and Friedlander "Pathogenesis and genetic control of resistance to the Sterne strain of <i>Bacillus anthracis</i> ." <i>Microb. Path.</i> 1988; 4: 53-69			
	65	Welkos <i>et al.</i> , "Differences in susceptibility of inbred mice to <i>Bacillus anthracis</i> " <i>Infect. Immun.</i> 1986; 51: 795-800			
	66	Yanagita, 1957, <i>Arch Mikrobiol</i> 26:329			
	67	Zeitlin <i>et al.</i> , "Tests of vaginal microbicides in the mouse genital herpes model." <i>Contraception</i> 1997; 56: 329-335.			
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Serial No.: 09/751,059  
Filed: JUN 25 2002 12/29/00  
Entitled: Antimicrobial Compositions And Methods Of Use

Group No.:  
Examiner:

**INFORMATION DISCLOSURE STATEMENT**

Assistant Commissioner for Patents  
Washington, D.C. 20231

**CERTIFICATE OF MAILING UNDER 37 CFR § 1.8(a)**

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to the: Assistant Commissioner for Patents, Washington, D.C. 20231, on June 19, 2002.

By: \_\_\_\_\_

Mary Ellen Waite

Sir or Madam:

The citations listed below, copies attached, may be material to the examination of the above-identified application, and are therefore submitted in compliance with the duty of disclosure defined in 37 C.F.R. §§ 1.56 and 1.97. The Examiner is requested to make these citations of official record in this application.

The following printed publications are referred to in the body of the specification:

- U.S. Patent 4,895,452
- U.S. Patent 5,103,497
- U.S. Patent 5,510,104
- U.S. Patent 5,547,677
- U.S. Patent 5,549,901
- U.S. Patent 5,618,840
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- Burdon *et al.*, "Experimental infection of mice with *Bacillus cereus*: studies of pathogenesis and pathologic changes." *J. Infect. Dis.* 1967; 117: 307-316.
- Burdon and Wende. "On the differentiation of anthrax bacilli from *Bacillus cereus*." *J. Infect. Dis.* 1960; 107: 224-234.
- Chatlynne *et al.*, "A lipid emulsion with effective virucidal activity against HIV-1 and other common viruses." *Foundation for Retrovirology and Human Health*, 3rd Conference on Retroviruses and Opportunistic Infections, Washington D.C., U.S.A., 1996; Abstract #351. This reference is a book and is not being submitted at this time but if the Examiner requests the reference it will be submitted.
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- Drobniewski "Bacillus cereus and related species." *Clin. Microbiol Rev.* 1993; 6: 324-338.

- Eriksson *et al.*, "Virus validation of plasma-derived products produced by Pharmacia, with particular reference to immuno Globulins." *Blood Coagulation and Fibrinolysis* 1994; 5 (Suppl. 3): S37-S44. This reference is a book and is not being submitted at this time but if the Examiner requests the reference it will be submitted.
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- Franz *et al.*, "Clinical recognition and management of patients exposed to biological warfare agents." *JAMA* 1997; 278: 399-411.
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- Goodman & Gilman's "The Pharmacological Basis of Therapeutics" Eds. Hardman *et al.*, 9th Edition, Publ. McGraw Hill, 1996; chapters 43 through 50. This reference is a book and is not being submitted at this time but if the Examiner requests the reference it will be submitted.
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- Halvorson and Church, *Bacteriol Rev* 1957, 21:112
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- Lamanna and Jones "Lethality for mice of vegetative and spore forms of *Bacillus cereus* and *Bacillus cereus*-like insect pathogens injected intraperitoneally and subcutaneously." *J. Bact.* 1963; 85: 532-535.
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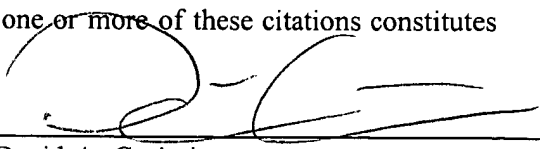
- Shibata "Germination of inactivated spores of *Bacillus cereus* T. Effect of preincubation with L-alanine or inosine on the subsequent germination." *Japan. J. Microbiol.* 1976; 20: 529-535.
- Smith *et al.*, "Dihydropyrancarboxamides related to Zanamivir: a new series of inhibitors of influenza virus sialidases. 1. Discovery, synthesis biological activity, and structure-activity relationships of 4-guanidino and 4-amino-4H-pyran-6-carboxamides." *J Med Chem* 1998; 41: 787-797.
- Titball and Manchee "Factors affecting the germination of spores of *Bacillus anthracis*." *J. Appi. Bact.* 1987; 62: 269-273.
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- Yanagita, 1957, *Arch Mikrobiol* 26:329
- Zeitlin *et al.*, "Tests of vaginal microbicides in the mouse genital herpes model." *Contraception* 1997; 56: 329-335.

Applicants have become aware of the following printed publications which may be material to the examination of this application:

- U.S. Patent 6,015,832
- U.S. Patent 6,361,787
- U.S. Patent 6,348,187

This Information Disclosure Statement under 37 C.F.R. §§ 1.56 and 1.97 is not to be construed as a representation that a search has been made, that additional information material to the examination of this application does not exist, or that any one or more of these citations constitutes prior art.

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